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10/820,659	04/08/2004	Gregory S. Kelley	1001.1755101	8007

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MINNEAPOLIS, MN 55403-2420

EXAMINER
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KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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07/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/820,659

Applicant(s)

KELLEY, GREGORY S.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 19-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges Applicant's reply filed 5/04/2007 in which no claims were amended, currently claims 1-38 are pending for examination with claims 19-38 withdrawn from a previous election restriction.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 and 7 rejected under 35 U.S.C. 102(e) as being anticipated by Deniega et al. (US2004/0064129). Deniega et al. discloses a catheter for uniform delivery of medication.

Regarding claims 1-4 and 7, Deniega et al. discloses a medical device comprising a first component (282) having an outer surface including an outer engagement portions, a second component (280) having an inner surface including an inner engagement portion wherein the inner engagement portion configured to fit over the outer engagement portion and an aerated adhesive layer ([0107-0109]) positioned between the inner engagement portion and the outer engagement portion (see figure 26A).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6 are rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. (US2001/002666). Deniega et al. meets the claim limitations as described above except a light curable epoxy aerated adhesive.

However, Ferrera et al. teaches a variable stiffness optical fiber shaft.

Regarding claims 5-6, Ferrera et al. teaches catheter components that are assembled with an aerated light curable epoxy adhesive ([0014]).

At the time of the invention, it would have been obvious to use the adhesive of Ferrera et al. to assemble the catheter of Deniega et al. because the light curable adhesive allows for increased joining flexibility. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Ferrera et al.

### ***Claim Rejections - 35 USC § 103***

Claims 8 and 13 are rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. (US2001/002666). The modified Deniega et al. meets the claim limitations except for the specific voids and densities.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the aerated-adhesive with the void space and density as claimed by Applicant for optimal joining performance, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Claim Rejections - 35 USC § 103***

Claims 9-12 are rejected under 35 U.S.C 103(a) as being unpatentable over in Deniega et al. in view of Jauchen et al. (6,180,544). Deniega et al. meets the claim limitations as described above except for the specific voids filled with inert N<sub>2</sub> gas and various pressures.

However, Jauchen et al. teaches an air-permeable substrate material with a self-adhesive coating process for its production and its use.

Regarding claims 9-12, Jauchen et al. teaches the use of an adhesive process to assemble medical devices that uses various noble gases (N<sub>2</sub>) and discusses various pressure and joining temperatures (cols 1-2).

At the time of the invention, it would have been obvious to use the adhesive of Jauchen et al. with the catheter of Deniega et al. because the adhesive allows for improved joining. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Jauchen et al.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the adhesive at the specific pressure, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Claim Rejections - 35 USC § 103***

Claims 14-15 are rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. Deniega et al. meets the claim limitations as described above except for the specific adhesive layer thickness.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the adhesive layer to desired thickness for optimal joining and reliability, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

***Claim Rejections - 35 USC § 103***

Claims 16-18 are rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Klima et al. (US2001/0020161). Deniega et al. meets the claim limitations as described above except for the specific catheter components.

However, Klima et al. teaches a catheter support structure.

Regarding claims 16-18, Klima et al. teaches a catheter with a hub (12), strain relief (22), and elongate shaft (20) (see Figure 1).

At the time of the invention, it would have been obvious to incorporate the strain relief and hub of Klima et al. to the system of Deniega et al. in order to allow for catheter reliability and strain control. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Klima et al.

***Response to Arguments***

Applicant's arguments filed 5/04/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that an aerated adhesive is not disclosed in Deniega et al. (2004/0064129) and that the combination of references with the Deniega et al. are improper.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Applicant's Representative argues that the adhesive of Deniega et al. is not an aerated adhesive, Examiner disagrees, Applicant's specification lacks any specific definition of an aerated adhesive, Examiner asserts that any mentioned biocompatible medical adhesive with have some air voids present within the layer during manufacture and assembly and therefore qualifies as an aerated adhesive using the broadest reasonable definition; Examiner suggests the addition of a product-by-process limitation to overcome the prior art of record. Regarding the combination of references, Deniega et al. ([0025, 0108]) mentions tubing overlap lengths in order to maximize tubing strength, the additionally cited references are in the same field of endeavor (medical delivery of therapeutic agents to a patient) and the use of superior adhesives to allow for this product would be obvious to one skilled in the art in order to maintain efficacy.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/19/2003

Christopher D. Koharski  
AU 3763CATHERINE S. WILLIAMS  
PRIMARY EXAMINER